

REMARKS

Claims 4-7, 9-13, 15 and 78-83 pending and stand rejected. Claims 15, 70 and 84-88 have been withdrawn from consideration. Claims 1-3, 8, 14, 16-69 and 71-77 have been cancelled. Careful consideration has been given to the grounds for rejection, and the following amendment and discussion are offered in response. No new matter has been added by way of these amendments and support for them may be found in the claims as originally filed as well as through out the specification. Reconsideration is respectfully requested.

Supplemental Action

Applicants note that the present Action was sent as a supplement to the Action mailed October 6, 2004. Applicants thank the Office for restarting the term for responding to the supplemental Action to run from December 2, 2004.

Election

Applicants acknowledge the restriction and election previously made and that claims 4-7, 9-13 and 78-83 are under consideration in the instant application.

Sequence Compliance

The Office objected to the specification because the sequences disclosed in the figures were not accompanied by the required sequence identification numbers. Applicants have amended the description of the drawings to supply these sequence identification numbers. As such, Applicants submit that this objection has been overcome.

Specification

The Office objected to the specification because it allegedly contained embedded hyperlinks. The objected to text has been deleted from the specification. The Office also objected to the Brief Description of the Drawings because it did not refer to Figure 4B or Figures 25A-25C. Also, the Office requested a new title for the present application. The Description of the Drawings and the

title were amended in accordance with the Office's suggestions. Accordingly, withdrawal of this objection is requested.

Formal Claim Objections

In accordance with the Office's formal objections to claims 4, 11, and 12, Applicants have amended these claims to delete the period immediately following the phrase "SEQ ID NO". Accordingly, withdrawal of this objection is requested.

Statutory Matter

Claims 4 and 9 were rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. Claims 4 and 9 have been amended to recite an isolated antibody or antibody fragment thereof. By adding the term "isolated" Applicants distinguish the claimed subject matter for antibodies existing in nature. As such, these clarifying amendments explicitly establish the claimed subject matter as matter which may be patented under the auspices of U.S. patent law. Accordingly, Applicants request the withdrawal of this rejection.

Supported by a Specific and Substantial Utility

Claims 4-7, 9-13 and 78-83 were rejected under both 35 U.S.C. §§ 101 and 112, first paragraph, allegedly because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Applicants respectfully disagree.

The presently claimed invention is supported by a well-established utility. Specifically, the claimed subject matter is useful to detect or treat a cancer that expresses the 108P5H8 gene. As noted in the specification, SEQ ID NO: 2570 is expressed in prostate cancer. For example, as shown in Figures 11, 12, 13 and 16 of the specification, all samples of prostate cancer tested express this protein. As such, the claimed subject matter is useful for the immunotherapeutic treatment of prostate cancer.

The Office also based the present rejection, in part, on the observation that the specification does not teach the significance or functional characteristics of the 108P5H8 polypeptide or antibody thereto. The Office is mistaken in that the specification clearly teaches that the 108P5H8 polypeptide is useful as a marker for cancer. Moreover, antibodies specific for the 108P5H8

polypeptide can be used to detect prostate cancer. Thus, a credible, specific and substantial has been articulated for the claimed subject matter in that antibodies to the 108P5H8 polypeptide can be used for the detection and treatment of prostate cancer. It is inconsequential that the biochemical function of the 108P5H8 polypeptide is not emphasized in the specification because the invention is not directed to that subject matter.

The Office also alleged that the specification did not disclose any specific methods or working examples that teach the production or labeling of the claimed antibody. This assertion is without merit as those of ordinary skill in the art are well versed in the production and labeling of antibodies. An applicant for a patent need not and preferably will not disclose that which is already well known in the art. Applicants submit that the making and labeling of antibodies to a target are notoriously well known in the art. Thus, detailed disclosures regarding these processes are not required under even the broadest reading of 35 U.S.C. § 112.

The Office also argued that diagnosing or treating a 108P5H8-expressing cancer did not amount to a specific or substantial utility. Specifically, the Office asserted that assays to diagnose or treat 108P5H8-expressing cancers could be achieved with any antibody. Applicants respectfully disagree. First, contrary to the Office's position, not every antibody will bind to a 108P5H8-expressing cancer cell. Antibody binding is dependent on the antigen to which it binds, so an antibody to an antigen that is not present on the 108P5H8 protein would not bind. In contrast, the antibodies of the claimed invention are specific for the 108P5H8 protein. Thus, they are useful as an imaging agent or an immunotherapeutic agent.

Moreover, the 108P5H8 polypeptide is expressed in normal and cancerous prostate. However, this observation is not relevant to the use of this protein as a target for immunotherapy. In fact, such expression could easily contribute to the efficacy of the antibody, in that it would be even more likely to bind to a 108P5H8-expressing cancer, such as prostate cancer. The more copies of 108P5H8 on a target, the more likely an antibody against 108P5H8 would be to find the target.

The Office also argued that some articles have noted that mRNA levels do not always correlate exactly with protein expression levels. The Office goes on to extrapolate this observation and conclude, without any other supporting literature citations, that some percentage of genes are

transcribed but produce no detectable protein. In rebuttal, Applicants note that, contrary to the position taken by the Office, the central dogma of molecular biology still holds that overexpression of mRNA is a valid indicator of protein overexpression. This principle of molecular biology remains valid, notwithstanding the nearly seven year old observations made in the Haynes, et al. paper.

The Office further rejected claims 4-7, 9-13 and 78-83 as allegedly lacking enablement. The Office based this rejection on the reasoning that because the claim recites an antibody that binds to a protein having at least 90% identity to SEQ ID NO: 2570. The Office argued that one of ordinary skill in the art would have to engage in undue experimentation to practice the scope of the claimed subject matter. Applicants disagree. Nevertheless, solely to advance prosecution, the pending claims no longer recite the 90% identity language.

In light of these observations it is clear that the presently claimed invention is adequately supported by a credible, specific and substantial utility. Accordingly, Applicants respectfully request that the present rejection be withdrawn.

Enablement

Claims 78-83 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Office has alleged that one of ordinary skill in the art would have to engage in undue experimentation to make and use antibodies that bind to proteins having at least 90% identity to SEQ ID NO: 2570. Applicants respectfully disagree. Nevertheless, as discussed above, the complained of language in the pending claims has been deleted. According, the reasons for this rejection have been removed.

Written Description

Claims 4-7, 9-13 and 78-83 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Specifically, the Office has alleged that Applicants have not sufficiently described proteins having at least 90% identity to SEQ ID NO: 2570. Applicants respectfully disagree. Nevertheless, as discussed above, the complained

of language in the pending claims has been deleted. According, the reasons for this rejection have been removed.

Indefiniteness

Claims 4-7, 9-13, and 78-83 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office has objected to the phrase “specifically binds”. Applicants submit that those of ordinary skill in the immunological arts would readily understand that the phrase “specifically binds” refers to an antibody that preferentially binds to a protein of SEQ ID NO: 2570. Applicants also submit that the phrase in question is notoriously well known in the art and that therefor it was definite on its face.

The Office also rejected these claims for reciting the word “thereof” in connection with antibody fragments. The relevant claims have been amended to clarify the subject matter Applicants regard as the invention. In light of the amendments and remarks above, Applicants request that the present rejection be withdrawn.

Anticipation

Claim 4 was rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Murgia, *et al.* To be anticipatory, a reference must teach or suggest each and every limitation of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Here, pending claim 4 recites an isolated antibody or antibody fragment that specifically binds to a protein having an amino acid sequence of SEQ ID NO: 2570. As noted in the Action, Murgia, *et al.* only teaches a sequence that has 91.2% sequence identity to SEQ ID NO: 2570. Because the cited reference does not teach each and every limitation of the claimed invention, it does not anticipate claim 4. Accordingly, the present rejection should be withdrawn.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 511582002500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: February 25, 2005

Respectfully submitted,

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